

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

IN RE HAIN CELESTIAL HEAVY METALS
BABY FOOD LITIGATION

Case No. 2:21-cv-00678-NM-AYS

The Honorable Nina Morrison

Served: November 7, 2022

**MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS
PLAINTIFFS' CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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TABLE OF CONTENTS

INTRODUCTION	1
BACKGROUND	3
I. Allegations of the Complaint	3
II. The Staff Report and the FDA’s “Closer to Zero” Initiative	5
ARGUMENT	7
I. This Court Should Dismiss This Action in Deference to the FDA’s Primary Jurisdiction and Its Ongoing “Closer to Zero” Initiative.	7
A. Plaintiffs’ claims implicate the FDA’s technical and scientific expertise, as well as issues that are particularly within the FDA’s discretion	8
B. Allowing this case to proceed creates a risk of inconsistent rulings	10
C. The “prior applications” factor also favors dismissal of this action.	12
II. This Court Should Dismiss Plaintiffs’ Lawsuit Under Rule 12(b)(1), as Plaintiffs Have Not Alleged a Cognizable Injury-in-Fact Sufficient to Establish Article III Standing.	13
A. Plaintiffs have not plausibly alleged that they or their children suffered any physical injury as a result of consuming Hain Celestial’s baby foods	13
B. Plaintiffs have not plausibly alleged that they suffered any economic injury as a result of purchasing Hain Celestial’s baby foods	17
C. Plaintiffs lack standing to seek injunctive relief.	21
III. This Court Should Dismiss Plaintiffs’ Lawsuit Under Rule 12(b)(6) Because Plaintiffs Have Not Plausibly Alleged That Hain Celestial’s Labeling Is Misleading	22
A. Plaintiffs have not plausibly alleged that Hain Celestial misleads consumers by failing to disclose the presence of naturally occurring heavy metals—which are ubiquitous throughout the entire food supply—in the Earth’s Best products.	23
B. Plaintiffs have not plausibly alleged that the presence of naturally- occurring heavy metals renders Hain Celestial’s labeling claims false or misleading.	25
C. Several of the claims Plaintiffs challenge are non-actionable puffery.	27
D. Plaintiffs’ challenges to the phrase “USDA Organic” are preempted.	29

CONCLUSION.....	30
-----------------	----

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.</i> , 621 F.3d 781 (8th Cir. 2010)	29
<i>Backus v. Gen. Mills, Inc.</i> , 122 F. Supp. 3d 909 (N.D. Cal. 2015)	10
<i>Beardsall v. CVS Pharmacy, Inc.</i> , 953 F.3d 969 (7th Cir. 2020)	24
<i>Belcastro v. Burberry Ltd.</i> , No. 16-1080, 2017 WL 5991782 (S.D.N.Y. Dec. 1, 2017)	19
<i>Berni v. Barilla S.p.A.</i> , 964 F.3d 141 (2d Cir. 2020).....	22
<i>Bildstein v. MasterCard Int’l, Inc.</i> , 329 F. Supp. 2d 410 (S.D.N.Y. 2004).....	24
<i>Birdsong v. Nurture, Inc.</i> , 275 F. Supp. 3d 384 (E.D.N.Y. 2017)	30
<i>Boysen v. Walgreen Co.</i> , No. 11-6262, 2012 WL 2953069 (N.D. Cal. July 19, 2012)	16, 21
<i>Buonasera v. Honest Co.</i> , 208 F. Supp. 3d 555 (S.D.N.Y. 2016).....	22
<i>Canale v. Colgate-Palmolive Co.</i> , 258 F. Supp. 3d 312 (S.D.N.Y. 2017).....	12
<i>Cent. States S.E. & S.W. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.</i> , 433 F.3d 181 (2d Cir. 2005).....	22
<i>Chuang v. Dr. Pepper Snapple Grp., Inc.</i> , No. 17-1875, 2017 WL 4286577 (C.D. Cal. Sept. 20, 2017)	27
<i>Colella v. Atkins Nutritionals, Inc.</i> , 348 F. Supp. 3d 120 (E.D.N.Y. 2018)	8, 10
<i>Cosgrove v. Blue Diamond Growers</i> , No. 19-8993, 2020 WL 7211218 (S.D.N.Y. Dec. 7, 2020)	23

<i>Coyle v. Hornell Brewing Co.</i> , No. 08-2797, 2010 WL 2539386 (D.N.J. June 15, 2010).....	9, 12
<i>Davis v. Hain Celestial Grp., Inc.</i> , 297 F. Supp. 3d 327 (E.D.N.Y. 2018)	22
<i>De Lacour v. Colgate-Palmolive Co.</i> , No. 16-8364, 2017 WL 6550690 (S.D.N.Y. Dec. 22, 2017)	12
<i>Doss v. Gen. Mills, Inc.</i> , 816 F. App'x 312 (11th Cir. 2020)	20
<i>Elkind v. Revlon Consumer Prod. Corp.</i> , No. 14-2484, 2015 WL 2344134 (E.D.N.Y. May 14, 2015)	22
<i>Ellis v. Tribune Television Co.</i> , 443 F.3d 71 (2d Cir. 2006).....	7, 8, 11
<i>Fink v. Time Warner Cable</i> , 714 F.3d 739 (2d Cir. 2013).....	22
<i>Fink v. Time Warner Cable</i> , 810 F. Supp. 2d 633 (S.D.N.Y. 2011).....	28
<i>Forsher v. J.M. Smucker Co.</i> , No. 15-7180, 2016 WL 5678567 (E.D.N.Y. Sept. 30, 2016)	8
<i>Fraker v. KFC Corp.</i> , No. 06-1284, 2006 WL 8430934 (S.D. Cal. Oct. 19, 2006)	28
<i>Friends of the Earth, Inc. v. Laidlaw Envt'l Servs, Inc.</i> , 528 U.S. 167 (2000).....	13
<i>In re Fruit Juice Prods. Mktg. & Sales Practices Litig.</i> , 831 F. Supp. 2d 507 (D. Mass. 2011)	16, 19
<i>Gaminde v. Lang Pharma Nutrition, Inc.</i> , No. 18-300, 2019 WL 1338724 (N.D.N.Y. Mar. 25, 2019)	14
<i>Gen. Elec. Co. v. MV Nedlloyd</i> , 817 F.2d 1022 (2d Cir. 1987).....	7
<i>In re Gen. Mills Glyphosate Litig.</i> , No. 16-2869, 2017 WL 2983877 (D. Minn. July 12, 2017)	25
<i>George v. Starbucks Corp.</i> , 857 F. App'x 705 (2d Cir. 2021)	28

<i>In re Gerber Prods. Co. Heavy Metals Baby Food Litig.</i> , No. 21-269, 2022 WL 10197651 (E.D. Va. Oct. 17, 2022).....	<i>passim</i>
<i>Gilleo v. J.M. Smucker Co.</i> , No. 20-2519, 2021 WL 4341056 (S.D.N.Y. Sept. 23, 2021)	23
<i>Harris v. Mondelēz Global LLC</i> , No. 19-2249, 2020 WL 4336390 (E.D.N.Y. July 28, 2020).....	22
<i>Herrington v. Johnson & Johnson Consumer Cos.</i> , No. 09-1597, 2010 WL 3448531 (N.D. Cal. Sept. 1, 2010)	14, 24
<i>In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices, & Prods. Liab. Litig.</i> , 903 F.3d 278 (3d Cir. 2018).....	17
<i>Kimca v. Sprout Foods, Inc.</i> , No. 21-12977, 2022 WL 1213488 (D.N.J. Apr. 25, 2022).....	<i>passim</i>
<i>Kimca v. Sprout Foods, Inc.</i> , No. 22-2538, 2022 WL 3586095 (N.J. Super. Ct. Aug. 5, 2022)	2, 9, 15
<i>In re KIND LLC “Healthy & All Natural” Litig.</i> , 209 F. Supp. 3d 689 (S.D.N.Y. 2016).....	8, 11
<i>In re KIND LLC “Healthy & All Natural” Litig.</i> , 287 F. Supp. 3d 457 (S.D.N.Y. 2018).....	12
<i>Koronthaly v. L’Oreal USA, Inc.</i> , 374 F. App’x 257 (3d Cir. 2010).....	16, 18
<i>Koronthaly v. L’Oreal USA, Inc.</i> , No. 07-5588, 2008 WL 2938045 (D.N.J. July 29, 2008)	16
<i>Lipton v. Nature Co.</i> , 71 F.3d 464 (2d Cir. 1995).....	28
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	13
<i>MacNaughten v. Young Living Essential Oils, LLC</i> , 575 F. Supp. 3d 315 (N.D.N.Y. 2021).....	29
<i>Marentette v. Abbott Labs, Inc.</i> , 201 F. Supp. 3d 374 (E.D.N.Y. 2016)	29, 30
<i>Nat’l Commc’ns Ass’n, Inc. v. AT&T Co.</i> , 46 F.3d 220 (2d Cir. 1995).....	8

<i>Nemphos v. Nestle Waters N. Am., Inc.</i> , 775 F.3d 616 (4th Cir. 2020)	11
<i>Nicosia v. Amazon.com, Inc.</i> , 834 F.3d 220 (2d Cir. 2016).....	13, 21
<i>Organic Consumers Ass’n v. Hain Celestial Grp., Inc.</i> , 285 F. Supp. 3d 100 (D.D.C. 2018)	30
<i>Parks v. Ainsworth Pet Nutrition, LLC</i> , 377 F. Supp. 3d 241 (S.D.N.Y 2019).....	24
<i>Pizza Hut, Inc. v. Papa John’s Int’l, Inc.</i> , 227 F.3d 489 (5th Cir. 2000)	28
<i>In re Plum Baby Food Litig.</i> , No. 21-2417, 2022 WL 16552786 (D.N.J. Oct. 31, 2022)	<i>passim</i>
<i>Raymo v. FCA US LLC</i> , 475 F. Supp. 3d 680 (E.D. Mich. 2020).....	29
<i>Red v. Kraft Foods, Inc.</i> , No. 10-1028, 2012 WL 5504011 (C.D. Cal. Oct. 25, 2012).....	26, 27
<i>Reese v. Odwalla, Inc.</i> , 30 F. Supp. 3d 935 (N.D. Cal. 2014)	11
<i>Rivera v. Wyeth-Ayerst Labs.</i> , 283 F.3d 315 (5th Cir. 2002)	16
<i>Sabo v. Wellpet, LLC</i> , 282 F. Supp. 3d 1040 (N.D. Ill. 2017)	21
<i>Song v. Champion Petfoods, Inc.</i> , 27 F.4th 1339 (8th Cir. 2022)	26, 27
<i>Spokeo, Inc. v. Robins</i> , 578 U.S. 330 (2016).....	13
<i>Taradejna v. Gen. Mills, Inc.</i> , 909 F. Supp. 2d 1128 (D. Minn. 2012).....	12
<i>Time Warner Cable, Inc. v. DIRECTV, Inc.</i> , 497 F.3d 144 (2d Cir. 2007).....	28
<i>Tran v. Sioux Honey Ass’n Coop.</i> , No. 17-110, 2017 WL 5587276 (C.D. Cal. Oct. 11, 2017).....	10

<i>Wallace v. ConAgra Foods, Inc.</i> , 747 F.3d 1025 (8th Cir. 2014)	14
--------------------------------------------------------------------------------	----

<i>Yetter v. Ford Motor Co.</i> , 428 F. Supp. 3d 210 (N.D. Cal. 2019)	28
---------------------------------------------------------------------------------	----

Statutes

7 U.S.C. § 6501	29
-----------------------	----

7 U.S.C. § 6503	29
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21 U.S.C. § 393	8
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Other Authorities

65 Fed. Reg. 80548 (Dec. 21, 2000)	29
------------------------------------------	----

INTRODUCTION

In 2021, the staff of the House Subcommittee on Economic and Consumer Policy issued a report that purported to find elevated levels of heavy metals in virtually every manufacturer’s baby foods. The FDA quickly reassured the public that “children are not at an immediate health risk from exposure to toxic elements in foods.” Ex. 3.¹ As the FDA explained to consumers, heavy metals occur naturally in the soil in which *all* fruits, vegetables, and grains grow and are therefore “unavoidable in the general food supply.” Ex. 4. Indeed, those very same heavy metals are present in the vegetables in the produce aisle, the crops used in canned goods, and countless other products made from fruits, vegetables, and grains. But many plaintiffs nonetheless flocked to the courthouses and alleged that the naturally occurring heavy metals in these manufacturers’ baby foods—which are prevalent throughout the food supply and in drinking water—are so “toxic” that they are unsafe for children to consume, even in trace amounts. Those claims present issues that the FDA should address in the first instance, and they are meritless in any event.

At the outset, this Court should dismiss this case in deference to the FDA’s primary jurisdiction. The FDA is currently assessing appropriate “action levels” for heavy metals in baby foods as part of its “Closer to Zero” initiative. The name of this initiative reflects the commonsense reality that it is impossible to eliminate naturally occurring heavy metals from the food supply altogether. Rather, setting appropriate “action levels” for heavy metals involves technical considerations and policy judgments about how to reduce heavy metals in the food supply in a way that is feasible for industry and that does not deprive children of nutrients key to their health and development. Given the FDA’s ongoing consideration of this issue, its superior expertise, and the risk that this Court or a jury might reach conclusions inconsistent with those of the FDA, this Court

¹ All exhibits are attached to Hain Celestial’s concurrently-filed Request for Judicial Notice.

should dismiss this action while FDA completes the process of setting “action levels” for heavy metals in foods as part of its “Closer to Zero” initiative. Two courts have dismissed virtually identical “heavy metals” lawsuits against other baby food manufacturers in deference to the FDA. *See In re Gerber Prods. Co. Heavy Metals Baby Food Litig.*, No. 21-269, 2022 WL 10197651, at *11–15 (E.D. Va. Oct. 17, 2022); *Kimca v. Sprout Foods, Inc.*, No. 22-2538, 2022 WL 3586095, at *2–4 (N.J. Super. Ct. Aug. 5, 2022) (“*Kimca II*”). This Court should do the same.

Even if this Court were inclined to resolve their claims, Plaintiffs lack standing to bring this lawsuit because they have not plausibly alleged that they (or their children) have suffered any injury as a result of purchasing or consuming Hain Celestial’s baby foods. Even assuming for argument’s sake that Hain Celestial’s baby foods contain heavy metals, Plaintiffs have not plausibly alleged that their children face any concrete risk of physical harm as a result of consuming those products. And if Hain Celestial’s products pose no risk of physical harm, then Plaintiffs cannot plausibly allege that they suffered any cognizable economic injury as a result of purchasing those products. Three courts faced with virtually identical lawsuits have found that the presence of trace amounts of heavy metals in baby food does not amount to a physical injury, an economic injury, or any other cognizable injury-in-fact under Article III. *See In re Plum Baby Food Litig.*, No. 21-2417, 2022 WL 16552786, at *6–13 (D.N.J. Oct. 31, 2022); *Kimca v. Sprout Foods, Inc.* (“*Kimca I*”), No. 21-12977, 2022 WL 1213488, at *5–8 (D.N.J. Apr. 25, 2022); *Gerber*, 2022 WL 10197651, at *5. The reasoning of those cases applies with equal force here.

Finally, Plaintiffs’ claims against Hain Celestial fail on their merits. It is beyond dispute—and the FDA has recognized—that heavy metals can occur naturally in any food made with ingredients that grow in soil. Products made with those ingredients inevitably contain trace levels of heavy metals. For that reason, no reasonable consumer could expect baby foods made from

fruits, vegetables, and grains to be completely free of naturally occurring heavy metals. Plaintiffs cannot plausibly allege that Hain Celestial misled consumers by failing to disclose the presence of those heavy metals, which are ubiquitous throughout the food supply. And absent any plausible allegation that the presence of trace levels of heavy metals (which the FDA has deemed not to pose an immediate risk of harm to children) is material to reasonable consumers, Plaintiffs cannot establish that Hain Celestial was under any duty to disclose this fact to those consumers.

Similarly, Plaintiffs have not plausibly alleged that the purported presence of heavy metals renders any of the labeling claims on Hain Celestial's products false or misleading. The presence of heavy metals has no bearing on whether a product is "Non-GMO," whether it is "Free of Pesticides and Herbicides," or whether it is "USDA Organic." Plaintiffs' generalized allegation that these claims contribute to an aura of healthiness does not suffice to establish that any of these claims are false or misleading. Other claims Plaintiffs challenge are non-actionable puffery that would not mislead any reasonable consumer. And insofar as Plaintiffs challenge Hain Celestial's use of the phrase "USDA Organic," that claim is preempted because it necessarily conflicts with the USDA's decision to authorize Hain Celestial's use of this statement on the baby foods at issue.

There is no conceivable sense in which the trace levels of heavy metals in Hain Celestial's products resulted in any cognizable injury or rendered any of its labeling claims misleading. This Court should dismiss Plaintiffs' lawsuit with prejudice and without leave to amend.

BACKGROUND

I. Allegations of the Complaint.

Hain Celestial manufactures baby food products under its Earth's Best brand, including fruit and vegetable purees, rice cereal, and oatmeal. *See generally* Consol. Am. Class Action Compl. ("CAC") ¶¶ 23–41. Plaintiffs allege that these products contain "dangerously high levels" of heavy metals, including lead, arsenic, cadmium, mercury, and perchlorate. *Id.* ¶ 13; *see also id.*

¶¶ 71–80. Although Plaintiffs characterize these heavy metals as “toxins known to pose significant dangers to children with life-altering consequences” (*id.* ¶ 3), they do not allege that they—or their children—have suffered any physical harm as a result of consuming Hain Celestial’s baby foods. Instead, Plaintiffs allege that the presence of heavy metals in Hain Celestial’s baby foods renders its labeling false and misleading for two basic reasons:

First, Plaintiffs allege that Hain Celestial fails to “disclose that its Baby Foods include Toxic Heavy Metals and/or other toxins.” *Id.* ¶ 5. They allege that Hain Celestial “knew or should have known of the presence of Toxic Heavy Metals and/or other toxins in its Baby Food products,” but “omitted this material information from its product labels, marketing materials, and advertisements.” *Id.* ¶¶ 111–12. Plaintiffs repeatedly allege that Hain Celestial’s purported failure to disclose the presence of heavy metals resulted in an economic injury—*i.e.*, purchasing Earth’s Best products that they “would not have purchased,” “would have bought less of,” or “would have paid less for” had Plaintiffs known that the products contained heavy metals. *Id.* ¶¶ 212, 228, 236, 259, 280, 293, 306, 319, 332, 344, 356, 372, 383, 395, 407, 418, 430, 443, 455, 466.

Second, Plaintiffs allege that the presence of heavy metals renders a variety of labeling statements on the packaging of its Earth’s Best baby foods—including marketing puffery like “made with superior ingredients,” factually accurate claims like “Non-GMO,” and the USDA-approved claim “USDA Organic”—misleading. *Id.* ¶ 4. Plaintiffs do not allege that these claims are false—for example, that the Earth’s Best products contain genetically modified organisms or are not in fact “organic.” Rather, Plaintiffs allege that these claims “induce[] reasonable consumers to believe in the quality and safety of its products for consumption by infants and children” and thereby allow Hain Celestial to “charge[] a premium price for these alleged benefits.” *Id.* ¶ 5.

Based on these allegations, Plaintiffs assert causes of action for breach of express warranty,

breach of the implied warranty of merchantability, negligent misrepresentation, unjust enrichment, fraudulent concealment, and violations of numerous states’ consumer fraud statutes. *See id.* ¶¶ 151–468. Plaintiffs assert these claims on behalf of a nationwide class, as well as numerous state-specific subclasses of consumers. *See id.* ¶¶ 125–41.

II. The Staff Report and the FDA’s “Closer to Zero” Initiative.

Plaintiffs’ claims against Hain Celestial are premised in large part on a February 4, 2021 staff report by the House Subcommittee on Economic and Consumer Policy (the “Staff Report”), which purported to find that the baby foods sold by several of America’s largest manufacturers—not just Hain Celestial—contained “dangerous levels of toxic heavy metals.” *See* Ex. 1; *see also* CAC ¶ 13 (alleging that the House Subcommittee Report “affirmatively found that Hain’s products contain Toxic Heavy Metals and/or other toxins and that its internal specifications permit dangerously high levels”). On March 5, 2021, the FDA responded to the Staff Report by issuing a public statement in which it “reassure[d] parents and caregivers that at the levels we have found through our testing . . . children are not at an immediate health risk from exposure to toxic elements in foods.” Ex. 3. The FDA also attempted to place the Staff Report in context by explaining that heavy metals “are present in the environment, including in our air, water, and soil, and therefore are unavoidable in the general food supply.” Ex. 4.

On April 8, 2021, the FDA issued an initiative titled “Closer to Zero: Action Plan for Baby Foods.”² *See* Exs. 5 & 22. The FDA announced that it had set a schedule to propose binding “action levels” for the presence of certain elements in baby foods, to consult with stakeholders about those proposed levels, and to finalize the action levels in enforceable regulations. *See* Ex.

² A chronology of the FDA’s extensive efforts as part of its “Closer to Zero” initiative, which are reflected in Exhibits 2 through 22, is attached to Hain Celestial’s Request for Judicial Notice.

22. In “Phase 1,” scheduled to take place between April 2021 and April 2022, the FDA planned to propose action levels for lead in baby foods and evaluate data about arsenic in order to determine the appropriate action levels. *See id.* Consistent with its projected timing, the FDA issued draft action levels for lead in juice products in April 2022, in which it proposed setting action levels of 10 parts per billion for lead in apple juice and 20 parts per billion for lead in other juice products. *See Ex. 16.* The FDA also announced that it has made “significant progress in evaluating the science for arsenic and the dose-response of cadmium to establish interim reference levels.” *Ex. 22.* And to keep the public informed about the work it is performing, the FDA has held multiple meetings, including a meeting with environmental- and consumer-focused nonprofits on June 8, 2021, a public meeting on November 18, 2021, a public webcast on December 9, 2021, two meetings with interested stakeholders on April 6 and 7, 2022, and a webinar on June 14, 2022 to discuss its proposed action levels for lead in juice products. *See Exs. 7, 11, 12, 15, 19.*

In “Phase 2,” scheduled for April 2022 to April 2024, the FDA intends to finalize its action levels for lead, propose action levels for arsenic, and evaluate data about cadmium and mercury to propose appropriate action levels. *See Ex. 22.* In “Phase 3,” which is scheduled to commence after April 2024, the FDA will propose action levels for cadmium and mercury, finalize its action levels for arsenic, and reassess the progress it has made. *See id.* In both phases, the FDA will also test samples of baby food and release the results of its testing to the public and publish biennial exposure assessments to “toxic elements” for children. *See id.*

In its “Closer to Zero” plan, the FDA noted that it would establish “interim reference levels (IRLs) for certain toxic elements,” which “may be among the key factors that inform the development of the FDA’s proposed action levels for certain toxic elements in categories of baby foods.” *Ex. 22.* The FDA made clear that reducing the amount of heavy metals in baby food is a

“complicated and multifaceted” issue and that “[i]t is crucial to ensure that measures taken to limit arsenic, lead, cadmium, and mercury in foods do[] not have unintended consequences—like eliminating from the marketplace foods that have significant nutritional benefits or reducing the presence of one element while increasing another.” *Id.* And as “action levels are finalized,” the FDA stated that it would “continue the cycle of continual improvement . . . to evaluate whether downward adjustments of interim reference levels should be made; proposing new action levels, as appropriate; consulting with stakeholders on feasibility, achievability, and other issues; and adjusting (as needed) and finalizing action levels.” *Id.*

ARGUMENT

I. This Court Should Dismiss This Action in Deference to the FDA’s Primary Jurisdiction and Its Ongoing “Closer to Zero” Initiative.

The “central aim” of the doctrine of primary jurisdiction is “to allocate initial decisionmaking responsibility between courts and agencies and to ensure that they do not work at cross-purposes.” *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (citation and internal quotation marks omitted). “Recourse to the doctrine of primary jurisdiction is . . . appropriate ‘whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.’” *Id.* (citation and internal quotation marks omitted); *see also Gen. Elec. Co. v. MV Nedlloyd*, 817 F.2d 1022, 1026 (2d Cir. 1987) (noting that the doctrine applies “when Congress has entrusted the regulation of certain subject matter under a statute to an administrative agency”).

In the Second Circuit, the “inquiry has generally focused on four factors: (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency’s particular field of expertise; (2) whether the question at issue is particularly within the agency’s discretion; (3) whether there exists a substantial danger

of inconsistent rulings; and (4) whether a prior application to the agency has been made.” *Ellis*, 443 F.3d at 82–83 (citing *Nat’l Commc’ns Ass’n, Inc. v. AT&T Co.*, 46 F.3d 220, 222 (2d Cir. 1995)). All four factors weigh in favor of deferring to the FDA’s primary jurisdiction.

A. Plaintiffs’ claims implicate the FDA’s technical and scientific expertise, as well as issues that are particularly within the FDA’s discretion.

Determining appropriate thresholds for heavy metals in food products implicates “technical or policy considerations within the [FDA’s] field of expertise.” *Ellis*, 443 F.3d at 82–83. The FDA is uniquely well-suited not only to assess the purported risks associated with heavy metals, but also to balance those risks against the benefits of ensuring that babies consume a variety of nutritious foods. Indeed, the FDA has made clear that reducing the amount of heavy metals in baby food is a “complicated and multifaceted” issue and that “[i]t is crucial to ensure that measures taken to limit arsenic, cadmium, lead, and mercury in foods do[] not have unintended consequences—like eliminating from the marketplace foods that have significant nutritional benefits or reducing the presence of one element while increasing another.” Ex. 22.

Moreover, the FDA undoubtedly has expertise and discretion in food labeling matters. *See* 21 U.S.C. § 393(b)(2)(A) (noting that the FDA is charged with “protect[ing] the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled”). Many courts in the Second Circuit have agreed that the FDA’s special expertise in issues of food labeling weighs in favor of deferring to its primary jurisdiction. These courts—as well as courts outside the Second Circuit—have specifically held that determining whether the presence of “particular ingredients” renders a product’s label misleading lies “particularly within the FDA’s discretion.”³ *In re KIND*

³ *See also, e.g., Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 140–41 (E.D.N.Y. 2018) (staying claims challenging “Net Carbs” claims as misleading because “[t]he FDA extensively regulates food labeling and has promulgated rules regarding the precise types of nutrient content claims and disclosure requirements implicated by plaintiff’s claim”); *Forsher v. J.M. Smucker Co.*, No. 15-7180, 2016 WL 5678567, at *2–3 (E.D.N.Y. Sept. 30, 2016) (staying lawsuit involving “natural” labeling because “the

LLC “Healthy & All Natural” Litig., 209 F. Supp. 3d 689, 695 (S.D.N.Y. 2016).

Kimca II is directly on point. There, after a federal court dismissed the plaintiffs’ “heavy metals” lawsuit for lack of standing (*see Kimca I*, 2022 WL 1213488, at *1), the plaintiffs re-filed their lawsuit in state court. *See Kimca II*, 2022 WL 3586095, at *1–2. The state court then dismissed the lawsuit in deference to the FDA’s primary jurisdiction. The court observed that the plaintiffs’ claims “would require the Court to determine what levels of heavy metals in baby foods are safe and acceptable, and whether it is misleading for foods containing certain levels of heavy metals to make true labeling statements about their contents.” *Id.* at *3. “These questions,” the court explained, “present ‘technical matter[s] involving complex chemical considerations’ that are uniquely within the FDA’s expertise.” *Id.* (quoting *Coyle v. Hornell Brewing Co.*, No. 08-2797, 2010 WL 2539386, at *4 (D.N.J. June 15, 2010)) (alteration in original).

The *Kimca II* court also noted that these issues “fall squarely within the FDA’s authority to regulate both the safety and labeling of foods,” that the “FDA has already announced its plan to act on heavy metals in baby foods,” and that “failing to defer to the FDA . . . poses a danger that a court’s determination ‘will be inconsistent with that of other courts or with the FDA itself.’” *Id.* at *3–4 (quoting *Coyle*, 2010 WL 2539386, at *4). And while the plaintiffs attempted to “distinguish the FDA’s ongoing work on action levels from their claims regarding label statements,” the court found that this was a “false distinction,” as “guidance from the FDA on what constitutes a safe level of heavy metals in baby food is integral to determining whether any of Sprout’s label statements were misleading.” *Id.* at *3.

The *Gerber* court reached the exact same conclusion. While the court acknowledged that “the ultimate question of Defendant’s liability for alleged material omissions is within the

technical and policy issues raised by plaintiff’s claims [were] better situated to being addressed by the FDA than the courts”).

conventional experience of the Court,” it nonetheless found the question of “whether Defendant’s products were at risk of containing *harmful* levels of Heavy Metals is a technical and policy consideration within the FDA’s field of expertise.” *Gerber*, 2022 WL 10197651, at *13 (emphasis in original). As the court emphasized, “[t]he FDA has the expertise to evaluate research and determine what levels of Heavy Metals can be considered harmful and whether consumers should be informed of their presence through labeling.” *Id.* And while the plaintiffs asserted that the FDA’s proposed “action levels” for heavy metals may be insufficient to protect infants and children, the court declined to “substitute its judgment on what levels of Heavy Metals in baby food are safe for the FDA’s judgment.” *Id.* at *14.

Here too, given its unique expertise and authority in food labeling matters, the FDA is “better situated” than a court or a jury to determine the appropriate levels of heavy metals in food products and when manufacturers should be required to disclose trace amounts of heavy metals in their products. *Tran v. Sioux Honey Ass’n Coop.*, No. 17-110, 2017 WL 5587276, at *3 (C.D. Cal. Oct. 11, 2017); *see also, e.g., Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d 909, 934 (N.D. Cal. 2015) (“Whether a body of evidence sufficiently demonstrates that a particular amount of a chemical substance poses a serious public health risk is precisely the kind of expert question that agencies are better suited to answer than courts or juries.”). And there can be no dispute that the FDA is actively considering this issue, as it has already issued proposed “action levels” for fruit juices as part of its ongoing “Closer to Zero” initiative. *See* Ex. 16–17. This Court should accordingly dismiss this lawsuit in deference to the FDA’s primary jurisdiction.

B. Allowing this case to proceed creates a risk of inconsistent rulings.

“In the context of primary jurisdiction, the threat of inconsistent rulings may emerge when the issue before a court is simultaneously pending before an agency with authority over that same issue.” *Colella*, 348 F. Supp. 3d at 140–41. “Courts should be especially solicitous in deferring

to agencies that are simultaneously contemplating the same issues.” *Ellis*, 443 F.3d at 88.

Plaintiffs’ lawsuit asks this Court to consider whether Hain Celestial’s labeling is false and misleading in light of the presence of heavy metals. But that would conflict with the FDA’s ongoing consideration of appropriate “action levels” for heavy metals in baby foods. Even assuming the truth of Plaintiffs’ allegations (and the accuracy of the Staff Report), the FDA may well determine that the levels of heavy metals in Hain Celestial’s baby food products are below the “action levels” that the FDA will set as part of its ongoing “Closer to Zero” initiative and pose no material risk of harm. Given the FDA’s ongoing consideration of this issue, it would be imprudent to allow Plaintiffs to press forward with a lawsuit that would potentially require a jury (or the Court) to reach findings that are inconsistent with those of the FDA.

Moreover, courts have recognized that it is particularly appropriate to invoke the doctrine of primary jurisdiction when doing so will “help harmonize court rulings.” *In re KIND*, 209 F. Supp. 3d at 696. That is especially true given that Congress, by enacting the Nutrition Labeling & Education Act of 1990 (“NLEA”), has “grant[ed] . . . authority to the FDA to establish a uniform federal scheme of food regulation.” *Reese v. Odwalla, Inc.*, 30 F. Supp. 3d 935, 939 (N.D. Cal. 2014) (citation and internal quotation marks omitted); *see also Nemphos v. Nestle Waters N. Am., Inc.*, 775 F.3d 616, 620 (4th Cir. 2020) (noting that Congress enacted the NLEA “to develop a nationwide system of uniform nutrition labeling for covered foods”).

Here, the release of the Staff Report has led to a flurry of litigation against Hain Celestial and the other six manufacturers named in that report, raising the threat that different courts will reach different conclusions about whether the presence of heavy metals renders the labeling of baby food false or misleading. Thus, “[a]ny decision . . . regarding what level of Heavy Metals is harmful enough to require a warning label on the Baby Food products will likely result in a

patchwork of decisions that vary by location, court, manufacturer, and product, resulting in different labeling standards for substantially similar baby food products produced by different manufacturers.” *Gerber*, 2022 WL 10197651, at *14. Dismissing this case in deference to the FDA’s primary jurisdiction would minimize this risk. *See Coyle*, 2010 WL 2539386, at *4 (“The prospect that different labels would be permissible in different jurisdictions would impose a burden on this industry that may be alleviated if the FDA chooses to speak directly to the question.”); *Taradejna v. Gen. Mills, Inc.*, 909 F. Supp. 2d 1128, 1135 (D. Minn. 2012) (noting that “several recently-filed yogurt lawsuits throughout the country involve[d] the same or similar issues,” which “underscore[d] the importance of promoting uniformity by referral of this matter to the FDA”).

C. The “prior applications” factor also favors dismissal of this action.

“A ‘prior application’ exists when the agency is conducting an ongoing investigation, has initiated proceedings based on citizen petitions, or is otherwise currently reviewing the relevant questions.” *De Lacour v. Colgate-Palmolive Co.*, No. 16-8364, 2017 WL 6550690, at *4 (S.D.N.Y. Dec. 22, 2017). The test is not whether the parties have “formally made applications” to the agency, but instead whether “the agency’s work is underway.” *In re KIND LLC “Healthy & All Natural” Litig.*, 287 F. Supp. 3d 457, 465 (S.D.N.Y. 2018); *see Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 325 (S.D.N.Y. 2017) (finding that this factor “favors deferring decision to the FTC, given its ongoing investigation as to whether the claims at issue are supported”).

Here, the FDA has initiated an extensive “Closer to Zero” plan designed to reduce the amount of heavy metals in the food supply and to establish appropriate “action levels” for heavy metals in food products, including baby food. The FDA’s plan includes establishing action levels for lead (which the FDA proposed for juice products in April 2022), arsenic (which the FDA expects to propose between April 2022 and April 2024), and cadmium and mercury (which the FDA expects to propose after it sets action levels for lead and arsenic). *See Ex. 22* Given the

FDA’s ongoing work in establishing “action levels” for heavy metals, this Court should not upend that methodical process by allowing Plaintiffs to push forward with these claims. Instead, it should dismiss these proceedings while the FDA completes its work on its “Closer to Zero” initiative.

II. This Court Should Dismiss Plaintiffs’ Lawsuit Under Rule 12(b)(1), as Plaintiffs Have Not Alleged a Cognizable Injury-in-Fact Sufficient to Establish Article III Standing.

Even if this Court is not inclined to dismiss this lawsuit in deference to the FDA’s primary jurisdiction, it should dismiss this lawsuit because Plaintiffs have not alleged a cognizable physical or economic “injury in fact”—as Article III requires. *See generally Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 239 (2d Cir. 2016).

“To establish injury in fact, a plaintiff must show that he or she suffered ‘an invasion of a legally protected interest’ that is ‘concrete and particularized’ and ‘actual or imminent, not conjectural or hypothetical.’” *Spokeo*, 578 U.S. at 339 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). “For each form of relief sought, a plaintiff ‘must demonstrate standing separately.’” *Nicosia*, 834 F.3d at 239 (quoting *Friends of the Earth, Inc. v. Laidlaw Envt’l Servs, Inc.*, 528 U.S. 167, 185 (2000)). Plaintiffs cannot satisfy this standard, as they cannot establish that the naturally-occurring heavy metals in Hain Celestial’s baby foods caused any physical harm or that they suffered any economic injury. Nor have they plausibly alleged that they face a risk of *future* harm, as Article III requires for them to seek injunctive relief.

A. Plaintiffs have not plausibly alleged that they or their children suffered any physical injury as a result of consuming Hain Celestial’s baby foods.

Throughout their complaint, Plaintiffs refer to arsenic, cadmium, lead, mercury, and perchlorate as “Toxic Heavy Metals,” and they allege that these substances are “dangerous at any level.” CAC ¶ 16; *see also id.* ¶¶ 45–70 (alleging that there is “no safe level” of consumption of these substances for infants). Plaintiffs also allege that Hain Celestial’s baby foods contain

purportedly “dangerous” levels of heavy metals.⁴ *See id.* ¶¶ 71–80. But these allegations do not suffice to establish that Plaintiffs or their children suffered any physical harm—or even an increased *risk* of physical harm—as a result of consuming Hain Celestial’s baby foods. *See, e.g., Herrington v. Johnson & Johnson Consumer Cos.*, No. 09-1597, 2010 WL 3448531, at *3–4 (N.D. Cal. Sept. 1, 2010) (dismissing lawsuit premised on alleged presence of carcinogens in children’s bath products and holding that the plaintiffs’ allegations did not establish that “the amount of the substances in Defendants’ products have caused harm or create a credible or substantial risk of harm,” such that the “risk Plaintiffs plead is too attenuated,” “not sufficiently imminent,” and “too speculative and uncertain to confer Article III standing”) (internal quotation marks omitted).

For example, in *Kimca I*, the plaintiffs alleged that their children faced an “increased risk of adverse health consequences as a result of their consumption of the Baby Food Products.” 2022 WL 1213488, at *5. The court held that this allegation did not establish an injury-in fact. “[E]ven if Plaintiffs sufficiently alleged that they purchased products with elevated levels of heavy metals,” the court explained, that did “not support the conclusion that the consumption of these products

⁴ Because Plaintiffs did not test the products they purchased, they allege throughout their complaint that the products they purchased “contained (or had a material risk of containing) any level of Toxic Heavy Metals and/or other toxins or contaminants.” CAC ¶ 42; *see also, e.g., id.* ¶ 244 (alleging that Hain Celestial “concealed that the Baby Foods contained, or were at risk of containing, elevated levels of Toxic Heavy Metals and/or other toxins”). But even if one accepted as true Plaintiffs’ allegation that Hain Celestial’s products are “at risk of containing” heavy metals, that would not suffice to establish that the products Plaintiffs purchased *actually* contained heavy metals—as would be required to establish Article III standing. *See, e.g., Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir. 2014) (holding that the plaintiffs lacked standing to challenge “kosher” labeling where they “fail[ed] to show that any of the particular packages of Hebrew National beef they *personally purchased* contained non-kosher beef”) (emphasis added); *Gaminde v. Lang Pharma Nutrition, Inc.*, No. 18-300, 2019 WL 1338724, at *2 (N.D.N.Y. Mar. 25, 2019) (holding that the plaintiff lacked Article III standing because he failed to allege that the supplements he personally purchased had less “Omega-3 Krill Oil” than advertised). And Plaintiffs articulate no reason to believe that Hain Celestial’s products are *more* likely to contain heavy metals than any other products containing fruits, vegetables, or grains grown in the soil.

caused a substantially increased risk of future harm to their children.” *Id.* at *6.⁵

In so holding, the court rejected the plaintiffs’ allegations that the levels of heavy metals in the defendant’s baby foods exceeded the standards that the FDA and EPA had set for other products like water, and it emphasized that the plaintiffs had not articulated why “these are apt comparisons for use in the context of baby food.” *Id.* (noting that “courts have declined to use similar cross-product comparisons to establish injury at the motion to dismiss stage”). Even if the plaintiffs alleged “that the Baby Food Products contain heavy metals” and “that elevated levels of heavy metals can be unsafe and dangerous,” the court concluded that “these two allegations” did not “establish[] that the levels of heavy metals in the Baby Food products are unsafe.” *Id.* at *8.

Just one week ago, the court in *In re Plum Baby Food Litigation* reached the same conclusion. Like Plaintiffs here, the plaintiffs in *Plum* alleged that the defendant’s “baby food products contain heavy metals” and that “heavy metals can be unsafe and dangerous.” 2022 WL 16552786, at *9. But the court dismissed their claims and found that these allegations “fail[ed] to establish . . . that the levels present in the baby foods at issue are at dangerous levels and therefore are likely to cause physical harm.” *Id.* “Without that causal link,” the court concluded, “Plaintiffs cannot establish injury as required for Article III standing.” *Id.*

That reasoning applies with equal force here. Plaintiffs allege that Hain Celestial’s products contain heavy metals, which Plaintiffs describe as “toxic” and “dangerous.” In particular, Plaintiffs allege that the levels of heavy metals in the Earth’s Best products exceeded both the FDA and EPA’s standards for other products (such as drinking water, juice, and candy) and Hain

⁵ Following the dismissal of their lawsuit, the *Kimca* plaintiffs re-filed their case in New Jersey state court, which is not bound by Article III standing principles. But the state court nonetheless found that the plaintiffs’ failure to allege an injury in fact not only deprived them of Article III standing, but also meant that they could not establish an actual injury, which the court noted was a “substantive element” of their consumer fraud claims. See *Kimca II*, 2022 WL 3586095, at *4.

Celestial’s own internal specifications.⁶ *See generally* CAC ¶¶ 45–81, 94–100. But even if one credited Plaintiffs’ speculation that the levels of heavy metals in Earth’s Best baby foods exceeded these thresholds, that does not establish that the consumption of these foods resulted in any concrete physical injury or measurable risk of future harm.

Indeed, despite Plaintiffs’ suggestion to the contrary, the FDA has made clear that “children are not at an immediate health risk from exposure to toxic elements in foods.” Ex. 3; *see also Kimca I*, 2022 WL 1213488, at *7 (noting that “this statement weakens the inference that the amount of heavy metals in the Baby Food Products creates a substantial risk of danger to children”). Under similar circumstances, many courts have agreed that “plaintiffs who have not been injured by an allegedly defective product generally do not have standing to sue the product’s manufacturer.”⁷ *In re Fruit Juice Prods. Mktg. & Sales Practices Litig.*, 831 F. Supp. 2d 507, 512 (D. Mass. 2011). This Court should reach the same conclusion here.

⁶ Again, as the *Kimca I* court noted, these “cross-product comparisons” do not plausibly establish that the levels of heavy metals in Hain Celestial’s baby foods are even theoretically unsafe. 2022 WL 1213488, at *6. For example, the FDA has established a threshold of 100 parts per billion of lead in candy that is likely to be consumed infrequently by young children (Ex. 23), but it has proposed draft “action levels” of 10 parts per billion of lead in apple juice and 20 parts per billion of lead in other forms of juice (Ex. 16). These disparities not only illustrate the complexity of setting appropriate thresholds for heavy metals in different food products, but also show that the FDA has rejected Plaintiffs’ position that there is “no safe level for consumption of toxic heavy metals.” Compl. at 14 (heading capitalization omitted). Indeed, that is precisely why the FDA has named its plan to set action levels for heavy metals in baby foods “*Closer to Zero*.” *See* Ex. 22.

⁷ *See also, e.g., Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002) (holding that plaintiffs lacked standing to sue manufacturer of allegedly defective drug when they were “not among the injured”); *Boysen v. Walgreen Co.*, No. 11-6262, 2012 WL 2953069, at *7 (N.D. Cal. July 19, 2012) (holding that plaintiff lacked standing where he alleged “that arsenic and lead are harmful toxins, and that the products contain those toxins” but did “not expressly allege that the levels of lead and arsenic contained in defendant’s juices are likely to cause physical harm”); *Koronthaly v. L’Oreal USA, Inc.*, No. 07-5588, 2008 WL 2938045, at *4–5 (D.N.J. July 29, 2008), *aff’d*, 374 F. App’x 257 (3d Cir. 2010) (dismissing lawsuit premised on alleged presence of lead in lipstick for lack of standing and holding that “Plaintiff’s allegations of a potential future injury are too remote and abstract to qualify as a concrete and particularized injury”).

B. Plaintiffs have not plausibly alleged that they suffered any economic injury as a result of purchasing Hain Celestial’s baby foods.

Unable to allege that they or their children suffered any concrete physical harm as a result of consuming Hain Celestial’s baby foods, Plaintiffs attempt to manufacture an injury by alleging that they paid a “premium price” for Hain Celestial’s products. CAC ¶ 5; *see also, e.g., id.* ¶ 212 (“Plaintiffs and members of the class would not have purchased Defendant’s Baby Foods, would have bought less of the Baby Foods, or would have paid less for the Baby Foods, had they known that the products were unsafe and unsuitable for babies . . .”). But Plaintiffs cannot establish an economic injury simply by alleging that, “although they purchased [the products] at a given price, they later wished they had not done so.” *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices, & Prods. Liab. Litig.*, 903 F.3d 278, 288 (3d Cir. 2018). And while Plaintiffs suggest that Hain Celestial’s conduct deprived them of the benefit of the bargain and resulted in a “price premium” injury, their allegations do not plausibly support those purported injuries.

To the extent Plaintiffs allege a “benefit of the bargain” injury, that theory fails because Plaintiffs have not plausibly alleged that their children are at increased risk of physical injury. Nor have they alleged that Hain Celestial failed to provide the product it promised—baby food made from nutritious ingredients like apples, pears, sweet potatoes, and squash. And at least three federal courts have rejected this precise theory of injury in other consumer class actions alleging that baby food contained “excessive” amounts of heavy metals.

In *Kimca I*, the plaintiffs asserted that even if the alleged ingestion of heavy metals did not result in any physical injury to them and their children, it resulted in an *economic* injury because they would not have purchased Sprout’s baby foods, or would have paid less for them, if Sprout had disclosed additional information about the presence of heavy metals in those products. *Kimca*, 2022 WL 1213488, at *8. The court rejected this argument. It found that the plaintiffs had not

alleged a plausible “benefit of the bargain” injury because they had “not adequately alleged that their children are at risk of harm from the Baby Food Products,” that the products “did not perform their intended purpose,” or that “the products were worthless for any other reason.” *Id.* at *9. “[W]ithout any plausible allegations of future risk,” the court concluded, “the allegation that the Baby Food Products were worthless also falls apart.” *Id.*

Similarly, in *Gerber*, the plaintiffs—who purchased baby foods that allegedly contained excessive amounts of heavy metals—alleged that they suffered “economic harm resulting from their purchase of a product that was ‘worthless or worth less’ than the purchase price due to Defendant’s material omissions.” 2022 WL 10197651, at *5. The court rejected this theory of injury and found that it “runs afoul of logic.” *Id.* “[W]hen a plaintiff purchases a consumable good and uses it to her benefit,” the court explained, “there is no economic injury unless plaintiff alleges the product ‘failed to work for its intended purpose or was worth objectively less than what one could reasonably expect.’” *Id.* at *6 (quoting *Koronthaly*, 374 F. App’x at 259). But as the court noted, the plaintiffs did not allege that Gerber’s baby foods were the “cause of any reported injuries,” that their “children are at imminent risk of developing any specific ailment in the future because they consumed the Baby Food Products,” or that “the Baby Food Products failed to provide Plaintiffs’ children with nourishment or otherwise perform as intended.” *Id.* at *7–8. Even if the plaintiffs subjectively believed that the products contained unacceptable levels of heavy metals, the court concluded that this did not amount to an economic injury. *Id.* at *8.

And in *Plum*, the court applied the same reasoning in holding that the plaintiffs had not alleged a plausible economic injury resulting from their purchase of Plum’s baby foods, as the products Plaintiffs purchased fulfilled their “intended purpose[]” of “feed[ing] their children.” 2022 WL 16552786, at *7. That was particularly true, the court explained, in light of the FDA’s

admonition “that parents should not throw out their supply of packaged baby foods or eliminate certain foods to avoid toxic element,” which “suggests that the products are fulfilling their intended purpose of providing nourishment to babies and infants.” *Id.* And while the plaintiffs alleged that “the presence of heavy metals rendered the baby food products worthless,” the court found that this allegation did “not save their benefit of the bargain economic injury claim.” *Id.* at *8. “Without the factual support of adverse health consequences or plausible allegations of future risk,” the court explained, “Plaintiffs cannot assert that the products are valueless.” *Id.*

Kimca I, *Gerber*, and *Plum* are hardly outliers. For example, in *In re Fruit Juice*, the court rejected the plaintiffs’ allegation that they suffered a benefit-of-the-bargain injury when they purchased fruit juice that contained lead. 831 F. Supp. 2d at 512–13. As the court explained:

Because Plaintiffs are unable to show that *any* actual harm resulted from consumption of the fruit juice products, their allegation of “economic” injury lacks substance. The fact is that Plaintiffs paid for fruit juice, and they received fruit juice, which they consumed without suffering harm . . . The products had no diminished value due to the presence of the lead. Thus, Plaintiffs received the benefit of the bargain, as a matter of law, when they purchased these products.

Id. at 512. That reasoning applies with equal force here: absent any allegation that Hain Celestial failed to provide what it promised (*i.e.*, baby food made with the ingredients promised on the label), Plaintiffs cannot plausibly allege any “benefit of the bargain” injury.⁸

Plaintiffs’ attempt to plead a “price premium” injury fares no better. Like their “benefit of the bargain” theory, this theory requires Plaintiffs to allege that they “overpaid by some objective measure” for Hain Celestial’s baby foods. *Belcastro v. Burberry Ltd.*, No. 16-1080, 2017 WL 5991782, at *4 (S.D.N.Y. Dec. 1, 2017). But Plaintiffs have not alleged any increased risk of

⁸ Plaintiffs will likely rely on *In re Plum Baby Food Litigation*, in which a judge in the Northern District of California found that the plaintiffs plausibly alleged an injury-in-fact. *See* Ex. 24, at 1–2. But the *Plum* court devoted less than a paragraph to explaining its reasoning, and the *Gerber* court specifically declined to follow this decision and emphasized that it found the *Kimca* court’s reasoning “more persuasive” than that of the *Plum* court. *See Gerber*, 2022 WL 10197651, at *10.

physical injury resulting from the purported presence of heavy metals in Hain Celestial's baby foods, and they articulate no other reason that Hain Celestial's products would *objectively* be worth less than the price they paid. Absent a plausible factual allegation suggesting that the presence of naturally occurring heavy metals diminished the value of the food they purchased, Plaintiffs' allegation that "they would not have paid as much" for Hain Celestial's products "if they had known that they contained heavy metals" does not establish a price premium injury. *Kimca I*, 2022 WL 1213488, at *8; *see also, e.g., Gerber*, 2022 WL 10197651, at *9 (rejecting the plaintiffs' "price premium" theory); *Doss v. Gen. Mills, Inc.*, 816 F. App'x 312, 314 (11th Cir. 2020) (affirming dismissal of false advertising lawsuit for lack of standing and rejecting the plaintiff's allegation "that the presence of glyphosate lower[ed] the value of the Cheerios she purchased").

Plaintiffs' "price premium" theory also fails because they have not plausibly alleged that there were alternative products available that were cheaper and/or did not contain heavy metals. Although Plaintiffs identify three baby food manufacturers that allegedly received the Clean Label Project's "Purity Award," that does not establish that their products contain zero heavy metals; to the contrary, that award simply purports to identify those products "with the *lowest levels* of the contaminants when compared to other products in a given category." CAC ¶ 117 (emphasis added). Indeed, Plaintiffs' allegation that baby food can be produced without *any* heavy metals defies the FDA's finding that, because heavy metals "are present in the environment and may enter the food supply through soil, water or air . . . they cannot be completely avoided in the fruits, vegetables, or grains that are the basis for baby foods, juices, and infant cereals." Ex. 2. It is accordingly unsurprising that the House Subcommittee purported to find heavy metals in the baby foods manufactured by "seven of the largest manufacturers of baby food in the United States." Ex. 1. That is because it is *impossible* to eliminate all traces of heavy metals in the food supply.

Given the ubiquity of heavy metals in baby foods, Plaintiffs cannot establish that there are comparable options that are free of heavy metals—as they must to allege that those products would command a “price premium.” *See, e.g., Kimca I*, 2022 WL 1213488, at *8 (“Plaintiffs do not identify any other comparable, cheaper, or safer products to show that they, in fact, paid a premium for the Baby Food Products.”); *Boysen*, 2012 WL 2953069, at *7 n.9 (holding that the plaintiffs did not allege a plausible economic injury when “most if not all consumer fruit juices contain levels of lead and arsenic” and “it is not clear that alternative juices exist”); *Sabo v. Wellpet, LLC*, 282 F. Supp. 3d 1040, 1041–42 (N.D. Ill. 2017) (dismissing consumer fraud claim where the plaintiffs failed to allege that alternative products “exist in the market”). Even if Plaintiffs were correct that there are products with *lower* levels of heavy metals, that would not be sufficient in light of Plaintiffs’ assertion that “there is *no safe level* for consumption of toxic heavy metals.” CAC at 14 (emphasis added) (heading capitalization omitted). The absence of any comparable products that lack heavy metals is fatal to Plaintiffs’ “price premium” theory of injury.

C. Plaintiffs lack standing to seek injunctive relief.

Even if this Court concluded that Plaintiffs have suffered an injury-in-fact sufficient to give them Article III standing (which they have not), that does not entitle them to seek injunctive relief. “Although past injuries may provide a basis for standing to seek money damages, they do not confer standing to seek injunctive relief unless the plaintiff can demonstrate that she is likely to be harmed again in the future in a similar way.” *Nicosia*, 834 F.3d at 239. To that end, many courts in the Second Circuit have made clear that “past purchasers of a product” ordinarily lack standing to seek injunctive relief, as they are unlikely to suffer any injury “once they become aware that

they have been deceived.”⁹ *Berni v. Barilla S.p.A.*, 964 F.3d 141, 147 (2d Cir. 2020).

Here too, Plaintiffs are now aware that Hain Celestial’s baby foods contain heavy metals. Plaintiffs therefore lack standing to seek injunctive relief, as there is no further risk that they will be “misled” into thinking that Hain Celestial’s baby foods are free of heavy metals. It is irrelevant that *other* consumers may not know that these products contain heavy metals. “There is no exception to demonstrating future injury when the plaintiff is pursuing a class action,” and “the named plaintiffs must have standing in order to seek injunctive relief on behalf of the class.” *Buonasera v. Honest Co.*, 208 F. Supp. 3d 555, 564 (S.D.N.Y. 2016); *accord Cent. States S.E. & S.W. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.*, 433 F.3d 181, 199 (2d Cir. 2005) (noting that the named plaintiffs “must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent”). Absent any plausible allegation that *they* will be “deceived” again, Plaintiffs lack standing to seek injunctive relief.

III. This Court Should Dismiss Plaintiffs’ Lawsuit Under Rule 12(b)(6) Because Plaintiffs Have Not Plausibly Alleged That Hain Celestial’s Labeling Is Misleading.

Finally, leaving aside their failure to establish Article III standing, Plaintiffs’ lawsuit fails because they have not plausibly alleged that Hain Celestial’s labeling is materially misleading.

Although Plaintiffs assert claims under numerous states’ consumer fraud statutes, those statutes all require Plaintiffs to establish that Hain Celestial’s labeling is “likely to mislead a reasonable consumer acting reasonably under the circumstances.” *Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013); *see also Harris v. Mondelēz Global LLC*, No. 19-2249, 2020

⁹ *See also, e.g., Davis v. Hain Celestial Grp., Inc.*, 297 F. Supp. 3d 327, 339 (E.D.N.Y. 2018) (“To the extent that plaintiff was deceived by defendants’ products, he is now aware of the truth and will not be harmed again in the same way.”); *Elkind v. Revlon Consumer Prod. Corp.*, No. 14-2484, 2015 WL 2344134, at *3 (E.D.N.Y. May 14, 2015) (same).

WL 4336390, at *2 (E.D.N.Y. July 28, 2020) (applying “consumer protection statutes from forty states and the District of Columbia” and finding that the “critical issue” for each was “whether a reasonable consumer would be misled by Defendant’s statement”).¹⁰

Here, Plaintiffs claim not only that Hain Celestial misleads consumers by failing to disclose the presence of heavy metals in its baby foods, but also that the presence of heavy metals makes it misleading for Hain Celestial to use numerous labeling claims—such as “Non-GMO,” “USDA Organic,” and “Made with Superior Ingredients”—on the packaging of its baby foods. Both theories of deception are fatally flawed.

A. Plaintiffs have not plausibly alleged that Hain Celestial misleads consumers by failing to disclose the presence of naturally occurring heavy metals—which are ubiquitous throughout the entire food supply—in the Earth’s Best products.

Plaintiffs’ fraud-by-omission claims are premised on their allegation that “[r]easonable parents . . . would consider the mere risk of exposure to Toxic Heavy Metals and/or other toxins or contaminants a material fact when considering whether to purchase the Baby Foods.” CAC ¶ 17. But this allegation is implausible, as it ignores the fact—which the FDA has reiterated time and time again—that heavy metals “are present in the environment” and “cannot be completely avoided in the fruits, vegetables, or grains that are the basis for baby foods, juices, and infant cereals made by companies or by consumers who make their own foods.” Ex. 2. It also ignores the FDA’s finding that “children are not at an immediate health risk from exposure to toxic

¹⁰ Plaintiffs also assert common-law claims for breaches of express and implied warranty, negligent misrepresentation, unjust enrichment, and fraudulent concealment. *See* CAC ¶¶ 151–99, 232–45. Because these claims are premised on Plaintiffs’ core allegation that Hain Celestial’s labeling is materially misleading, “all of Plaintiffs’ claims must be dismissed” if Plaintiffs have not plausibly alleged “that the labeling of the [products] is misrepresentative or misleading.” *Cosgrove v. Blue Diamond Growers*, No. 19-8993, 2020 WL 7211218, at *3 (S.D.N.Y. Dec. 7, 2020); *see also Gilleo v. J.M. Smucker Co.*, No. 20-2519, 2021 WL 4341056, at *7 (S.D.N.Y. Sept. 23, 2021) (dismissing claims for breach of warranty, fraud, negligent misrepresentation, and unjust enrichment where the court held that the labeling was not misleading).

elements in foods”—including heavy metals. *Id.* Given the ubiquity of naturally-occurring heavy metals in the food supply and the absence of any health risks associated with the consumption of baby food, Plaintiffs cannot plausibly allege that the “mere risk of exposure” (CAC ¶ 17) to the naturally-occurring heavy metals in Hain Celestial’s baby foods is material to reasonable consumers—as Plaintiffs must allege to state plausible fraud-by-omission claim.¹¹

Parks v. Ainsworth Pet Nutrition, LLC, 377 F. Supp. 3d 241 (S.D.N.Y. 2019) is instructive. There, the plaintiff alleged that the defendant mislabeled its dog food as “natural” even though it contained trace amounts of glyphosate, the active ingredient in the herbicide Roundup. *Id.* at 244. The court dismissed this lawsuit, as the “presence of negligible amounts of glyphosate in a dog food product that do[es] not have harmful, ‘toxic,’ or ‘carcinogenic’ effects is not likely to affect consumers’ decisions in purchasing the product and is thus not material.” *Id.* at 248.

Similarly, in *Herrington*, the plaintiffs alleged that the defendants failed to disclose that their children’s bath products “contain probable carcinogens, other unsafe contaminants and ingredients that have not been shown to be safe,” and they claimed that they “would not have purchased the products” had they known the products contained formaldehyde and dioxane. 2010 WL 3448531, at *1. The court dismissed their lawsuit and found that the alleged non-disclosures were not material. *Id.* at *8. Absent any plausible allegation “that the levels of these substances caused them or their children harm,” the court found that “the alleged non-disclosures are not actionable” and held that they had not stated a plausible claim. *Id.*

Here too, Plaintiffs cannot plausibly allege that the presence of naturally occurring heavy

¹¹ See, e.g., *Bildstein v. MasterCard Int’l, Inc.*, 329 F. Supp. 2d 410, 414 (S.D.N.Y. 2004) (“A material claim is one that involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding, a product.”) (citations and alterations omitted); *Beardsall v. CVS Pharmacy, Inc.*, 953 F.3d 969, 972–73 (7th Cir. 2020) (noting that a “label is deceptive” only if it “is likely to mislead a reasonable consumer in a *material* respect”) (emphasis added).

metals is material to reasonable consumers. Given that heavy metals are generally present in varying degrees in *all* vegetables, grains, and other foods grown in the soil, no reasonable consumer would expect a food made from those ingredients to be completely free of heavy metals. *See In re Gen. Mills Glyphosate Litig.*, No. 16-2869, 2017 WL 2983877, at *6 (D. Minn. July 12, 2017) (“[I]t is not plausible to allege that the statement ‘Made with 100% Natural Whole Grain Oats’ means that there is no trace glyphosate in Nature Valley products It would be nearly impossible to produce a processed food with no trace of any synthetic molecule.”).

Nor have Plaintiffs plausibly alleged that there are realistic alternatives that are free of heavy metals. Because the Staff Report purported to find heavy metals in the baby foods manufactured by “seven of the largest manufacturers of baby food in the United States” (Ex. 1), it is implausible that the presence or absence of heavy metals is a factor that would influence consumers to purchase baby foods from one of these manufacturers as opposed to another. Indeed, the FDA admonished consumers that making baby food at home is “not likely to reduce your baby’s risk of exposure to toxic elements in food” and “may actually result in higher concentrations of toxic elements”—meaning that this is not a practical alternative either.¹² Ex. 5 Absent any plausible allegation that the presence of naturally-occurring heavy metals is material to reasonable consumers, Plaintiffs’ fraud-by-omission theory necessarily fails.

B. Plaintiffs have not plausibly alleged that the presence of naturally-occurring heavy metals renders Hain Celestial’s labeling claims false or misleading.

In addition to challenging Hain Celestial’s alleged failure to disclose the presence of heavy

¹² Indeed, Happy Babies Bright Futures—whose December 2017 report Plaintiffs cite to support their claims that Hain Celestial’s products contain “significant levels” of heavy metals (CAC ¶ 83)—issued a report in August 2022 that found “no evidence to suggest that homemade baby food has lower heavy metal levels than store-bought brands.” Ex. 25. This not only underscores the impracticality of homemade baby food as an alternative to store-bought baby food, but further confirms the ubiquity of heavy metals in *all* ingredients grown in the soil.

metals in its baby foods, Plaintiffs challenge a litany of labeling claims that have nothing to do with the presence or absence of heavy metals—such as “USDA Organic,” “Non-GMO,” and “Free of Preservatives.” But as court after court has made clear, a plaintiff cannot state a plausible consumer fraud claim by alleging that “a consumer will read a true statement on a package and will then . . . assume things about the products *other than* what the statement actually says.” *Red v. Kraft Foods, Inc.*, No. 10-1028, 2012 WL 5504011, at *3 (C.D. Cal. Oct. 25, 2012). And consistent with that commonsense principle, courts have repeatedly dismissed consumer fraud claims premised on the theory that the presence of an unwelcome substance renders truthful claims about a product false and misleading.

Plum is once again directly on point. There, the plaintiffs alleged that Plum misrepresented its baby foods as “safe,” “organic,” non-GMO,” “perfect,” “nutritious,” and “packed with essential vitamins and minerals,” even though they allegedly contained heavy metals. 2022 WL 16552786, at *8. But the court found this theory of deception implausible, as “[n]one of these descriptors relate to heavy metals.” *Id.* Moreover, the court noted, the plaintiffs did not allege “that any of these specific claims are not true,” as there were “no allegations that the baby food products at issue do not contain the vitamins and minerals that they claim to contain” or that “the ingredients are not non-GMO or not organic.” *Id.* Because “[a]ll of these claims could be true even with the presence of heavy metals within the products,” the court found that the alleged presence of heavy metals did not make these claims deceptive. *Id.*

Song v. Champion Petfoods, Inc., 27 F.4th 1339 (8th Cir. 2022), is also illustrative. There, the plaintiffs alleged that the defendant mislabeled its products as “biologically appropriate,” which allegedly “indicate[d] a complete absence of heavy metals like arsenic, cadmium, mercury, and lead.” *Id.* at 1344. The district court dismissed this claim, and the Eighth Circuit affirmed.

In so holding, the Eighth Circuit noted that the plaintiffs had not plausibly alleged that “the level of heavy metals present in Champion’s dog food is harmful to dogs” and that they did not “dispute that heavy metals occur naturally in meat and fish.” *Id.* The Eighth Circuit accordingly concluded that it “is simply not plausible to suggest that a reasonable consumer would read the phrase ‘biologically appropriate’ . . . and understand Champion to be representing that it eliminated all traces of heavy metals from the dog food.” *Id.* (citation and internal quotation marks omitted).

Here too, the fact that Hain Celestial’s baby foods may contain naturally-occurring heavy metals has no bearing on whether they are “Organic,” “Made with Superior Ingredients,” “Non-GMO,” or any of the other claims Plaintiffs challenge.¹³ Plaintiffs offer no reason, other than the alleged presence of heavy metals, that any of these factually accurate statements are misleading. And while Plaintiffs claim that these statements contribute to a general perception that Hain Celestial’s products are healthy and safe, that does not render any of these statements deceptive. *See, e.g., Red*, 2012 WL 5504011, at *3; *Chuang v. Dr. Pepper Snapple Grp., Inc.*, No. 17-1875, 2017 WL 4286577, at *4 (C.D. Cal. Sept. 20, 2017) (“Where statements or depictions of ingredients on packaging are truthful . . . courts may dismiss claims that those statements or depictions are misleading.”). Absent any plausible allegation that Hain Celestial’s labeling claims are in fact false, Plaintiffs have not stated a plausible claim against Hain Celestial.

C. Several of the claims Plaintiffs challenge are non-actionable puffery.

In addition to challenging factually accurate claims on the labeling of the Earth’s Best products (such as “Non-GMO,” “Free of Preservatives,” and “USDA Organic”), Plaintiffs also

¹³ These claims include: (1) “USDA Organic” and “Organic”; (2) “Non-GMO,” “Free of GMOs,” and “No Genetically Engineered Ingredients”; (3) “Free of Preservatives”; (4) “Free of Pesticides or Herbicides” and “Grown Without Potentially Harmful Pesticides or Herbicides”; (5) “Pure” and “Nurturing Baby the Purest Way”; and (6) “Made with Superior Ingredients.” CAC ¶¶ 4, 103.

challenge the statements “Pure,” “Nurturing Baby the Purest Way,” and “Made with Superior Ingredients.” *See* CAC ¶¶ 4, 103. But these claims are non-actionable puffery.

“Puffery includes generalized or exaggerated statements which a reasonable consumer would not interpret as a factual claim upon which he could rely.” *Fink v. Time Warner Cable*, 810 F. Supp. 2d 633, 644 (S.D.N.Y. 2011); *see also Lipton v. Nature Co.*, 71 F.3d 464, 474 (2d Cir. 1995) (noting that puffery includes “[s]ubjective claims about products, which cannot be proven either true or false”). As the Second Circuit has made clear, “puffery includes ‘a general claim of superiority over comparable products that is so vague that it can be understood as nothing more than a mere expression of opinion.’” *George v. Starbucks Corp.*, 857 F. App’x 705, 706 (2d Cir. 2021) (quoting *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 159 (2d Cir. 2007)).

“Made with Superior Ingredients” is a textbook example of this principle, as there is no objective way determine whether the ingredients in Hain Celestial’s products are “superior.” Hain Celestial’s broad claim that its products are “Made with Superior Ingredients” is accordingly not actionable. *See, e.g., Fraker v. KFC Corp.*, No. 06-1284, 2006 WL 8430934, at *3 (S.D. Cal. Oct. 19, 2006) (holding that “highest quality ingredients” was puffery); *Pizza Hut, Inc. v. Papa John’s Int’l, Inc.*, 227 F.3d 489, 498 (5th Cir. 2000) (holding that the phrase “Better Ingredients, Better Pizza” was puffery because “the phrases ‘better ingredients’ and ‘better pizza’ are not subject to quantifiable measures”); *Yetter v. Ford Motor Co.*, 428 F. Supp. 3d 210, 234 (N.D. Cal. 2019) (holding that claims about “superior gas mileage” were “quintessential, non-actionable puffery”).

The phrases “Pure” and “Nurturing Baby the Purest Way” are similarly non-actionable puffery. As with the claim that Earth’s Best Products are “Made with Superior Ingredients,” there is no objective way to determine whether a product is “Pure” or whether it “Nurtures Baby the Purest Way.” For that reason, courts have agreed that similar claims touting a product’s purity

constitute non-actionable puffery.¹⁴ This Court should reach the same conclusion here.

D. Plaintiffs’ challenges to the phrase “USDA Organic” are preempted.

Finally, even if Plaintiffs had plausibly alleged that the presence of heavy metals makes it misleading for Hain Celestial to highlight the positive attributes of its baby foods (which is false), their challenges to the phrase “USDA Organic” are preempted by federal law, as Plaintiffs’ claims necessarily challenge the USDA’s decision to authorize Hain Celestial’s use of this phrase.

Congress enacted the Organic Food Production Act (“OFPA”) to “establish national standards governing the marketing of certain agricultural products as organically produced products.” 7 U.S.C. § 6501(1). To that end, Congress instructed the USDA to “establish an organic certification program” for organic products and to “implement the program . . . through certifying agents” charged with implementing this program. 7 U.S.C. § 6503. The USDA subsequently established the National Organic Program, which sets forth regulations for when products can be labeled as “organic.” *See* 65 Fed. Reg. 80548 (Dec. 21, 2000).

Because the OFPA and the USDA’s National Organic Program regulations empower a “certifying agent” to determine whether a product can be labeled as “organic,” courts have consistently held that federal law preempts state-law claims challenging representations that a product is “organic,” as “any attempt to hold [a manufacturer] liable under state law based upon its products supposedly not being organic directly conflicts with the role of the certifying agent as set forth in § 6503(d).” *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781, 797 (8th Cir. 2010); *see also Marentette v. Abbott Labs, Inc.*, 201 F. Supp. 3d 374,

¹⁴ *See, e.g., MacNaughten v. Young Living Essential Oils, LLC*, 575 F. Supp. 3d 315, 327–30 (N.D.N.Y. 2021) (holding that “100% Pure, Therapeutic-Grade” was non-actionable puffery); *Raymo v. FCA US LLC*, 475 F. Supp. 3d 680, 706 (E.D. Mich. 2020) (holding that the statement “environmentally clean” was “general,” “nonquantifiable,” and “nonactionable puffery”).

385 (E.D.N.Y. 2016) (“Once the federal government, through a USDA-accredited certifying agent, permits a manufacturer to label a product as ‘Organic’ because it has met that standard, any allegation that the product is not truthfully labeled as such is a challenge to the certifying agent’s decision, *not* the manufacturer’s representation . . .”).

For this reason, many courts have dismissed virtually identical lawsuits alleging that infant formula and baby foods were mislabeled as “organic,” reasoning that these lawsuits were preempted by the OFPA and the USDA’s implementing regulations. *See Marentette*, 201 F. Supp. 3d at 385; *Birdsong v. Nurture, Inc.*, 275 F. Supp. 3d 384, 392–95 (E.D.N.Y. 2017) (applying the same reasoning in case involving Nurture infant and baby food products). Indeed, one court reached this conclusion in a case involving the very same Earth’s Best products at issue here. *See Organic Consumers Ass’n v. Hain Celestial Grp., Inc.*, 285 F. Supp. 3d 100, 103–08 (D.D.C. 2018). Here too, Plaintiffs’ claims do not simply challenge *Hain Celestial’s* use of the term “USDA Organic”; instead, they challenge *the USDA’s* decision to authorize the use of this term. Regardless of whether Plaintiffs believe that the naturally-occurring heavy metals in Hain Celestial’s baby foods render those products unsafe or unhealthy (which is false), Plaintiffs cannot hold Hain Celestial liable for using a claim that the USDA expressly permitted.

CONCLUSION

The Court should dismiss Plaintiffs’ lawsuit with prejudice and without leave to amend.

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Respectfully submitted,

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